

### **REMARKS/ARGUMENTS**

In response to the Office Action mailed December 28, 2004, Applicant submits the following amendments.

#### **Change of Title**

The Examiner has stated that the title of the invention is not descriptive and has requested a new title. Applicant has now changed the title to one that clearly indicates the nature of the present invention.

#### **Acknowledgment of Allowed Claims**

Allowance of Claims 30-44 is acknowledged.

#### **The Rejection Under 35 U.S.C. 102(a)**

The Examiner has rejected Claim 47 under 35 U.S.C. 102(a) as being anticipated by Choi, et al., U.S. Patent 6,103,759.

Applicant has now cancelled Claim 47.

#### **The Rejection Under 35 U.S.C. 103(a)**

The Examiner has rejected Claims 26, 29, 45, 46 and 48 under 35 U.S.C. 103(a) as being unpatentable over Bossinger et al., U.S. Patent 3,313,692.

The Examiner states "Bossinger teaches the administration of compounds of instant Formula II for inducing calming effect. See Example 1, column 4, as well as the second, eleventh and twelfth compounds in the table in column 9. Although there is no specific recitation directed to treating an Impulse Control Disorder, one skilled in the psychiatry art would have been motivated to administer a compound that induces a

calming effect. Producing a state in an individual that is free from agitation, excitement or disturbance is a treatment for Impulse Control Disorder”.

The Applicant respectfully traverses this rejection.

Bossinger does teach that administration of compounds of instant Formula II produces a “calming” effect. Bossinger does not elaborate or specifically define what the term “calming” means. However in Bossinger Column 1, line 21 the use of the term “calming” is equated to “sedation”. This is consistent with the expectation that many carbamate compounds known at the time (late 1960’s) were central nervous system depressants and were sedative-hypnotic compounds and their characteristic clinical effect in humans is to induce sedation and sleep. As the Examiner correctly notes, Bossinger contains no specific recitation directed to treating an Impulse Control Disorder (ICD). However, the Examiner contends that “one skilled in the psychiatry art” would be motivated to administer a compound that induces a “calming” effect because that would be treatment for an Impulse Control Disorder.

The Applicant respectfully disagrees with the Examiner’s contention.

The property of inducing sedation or calming and the property of controlling the impulsive behavior that is characteristic of an Impulse Control Disorder are separate clinically and from a biochemical and/or neurological prospective.

Of course, if an individual is given sufficient amount of a sedative-hypnotic compound they may become too sedated to “behave” in any way, including an impulsive manner. In fact, they may even be rendered unconscious. However, in general, sedative-hypnotic compounds do not specifically reduce impulsive behavior in patients with ICD and often may even worsen them. For example, many sedative-hypnotic drugs may produce a state of pathological intoxication in which extreme, often violent, impulsive behavior is seen. Benzodiazepines and barbiturates have this property and, of course, so does ethyl alcohol. Ethyl alcohol is a good example of a

CNS depressant or sedative-hypnotic drug that routinely produces an exacerbation of impulsive and even violent impulsive behavior during the early phase of intoxication.

On the other hand, two of the most effective drug treatments for ICD are carbamazepine (Tegretol) and lithium carbonate and these two compounds have minimal sedative-hypnotic properties but very effectively and specifically inhibit impulsive behavior in patients with ICD without affecting other mental functions.

Specifically, with regard to the claimed group of compound in the instant application the Applicants refer the Examiner to Paragraph 12 of the 132 Declaration of Boyu Zhao. Dr. Zhao specifically states "the anti-aggressive activity of test compound at 40 mg/kg P.O. was not related to sedation". (underlining added)

Therefore, Applicant submits that the beneficial effects in Impulsive Control Disorders of the group of compounds disclosed and claimed in the instant application is entirely separate from the sedating or calming effects that these compounds may or may not possess. These effects are surprising, unexpected and specific anti-impulsive properties and are in no way rendered obvious by the teaching of Bossinger.

Therefore, Applicant requests that Examiner withdraw the rejection of Claims 26, 29, 45, 46 and 48 under 35 U.S.C. 103(a).

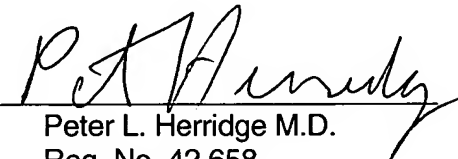
#### **The Objection to Claims 27 and 28**

In the Office Action summary, the Examiner has indicated that Claims 27 and 28 are objected to. However, this objection is not elaborated on in the body of the Office Action. Therefore, Applicants are not able to respond.

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Accordingly, the claims pending and under consideration are claims 26-46 and claim 48. Claims 30-44 have been allowed. Early favorable action on the merits is respectfully requested. Applicant respectfully requests a timely Notice of Allowance of claims 26-29 and claims 45, 46, and 48.

Respectfully submitted,

By:   
Peter L. Herridge M.D.  
Reg. No. 42,658

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-5352  
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